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Publication Title:

**A METHOD OF MANUFACTURING A FOIL-WRAPPED BREAST PROSTHESIS
AND A SHAPING TOOL FOR USE IN PERFORMING THE METHOD**

Abstract:

Abstract of WO9517141

When manufacturing a foil-wrapped breast prosthesis with a filling consisting of a curable compound, the curing is performed after placing a filled prosthesis bag, formed by contour welding of two joined foil sheets, in a mould cavity (6) without closing the mould cavity and maintaining vacuum at least in the beginning of the curing, whereby especially an increased degree of freedom is obtained with respect to shaping the rear side of the prosthesis, so that this, among other things, can be provided with thin edge parts for obtaining good fitting to the body. To ease the mounting of the bag and the accurate positioning of this in the mould cavity (6), the latter is formed in a first mould part (5) of a shaping tool, which furthermore comprises a tightening frame (10) having a packing (12), which provides an unambiguously oriented tightening of the bag when this is placed in the ed2 mould cavity (6).

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(21) International Application Number: PCT/DK94/00479 (22) International Filing Date: 21 December 1994 (21.12.94) (30) Priority Data: 1444/93 23 December 1993 (23.12.93) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Bronzevej 2.8, DK-3060 Esbjerg (DK). (72) Inventor; and (75) Inventor/Applicant (for US only): RASMUSSEN, Laurits, Boye [DK/DK]; Arent Hansensvej 23, Smidstrup, DK-3250 Gilleleje (DK). (74) Agents: RAFFNSØE, Knud, Rosenstand et al.; International Patent-Bureau, Høje Taastrup Boulevard 23, DK-2630 Taastrup (DK).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Danish).</i>	
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<div style="float: right; border: 1px solid black; padding: 5px; margin-top: 10px;"> <div style="border: 1px dashed black; padding: 2px; margin-bottom: 2px;">STITCHING ELEMENTS ON REAR FOIL</div> <div style="border: 1px dashed black; padding: 2px; margin-bottom: 2px;">PRE-SHAPING OF REAR FOIL</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">CONTOUR WELDING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">MARKING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">FILLING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">VENTILATION (MASSAGING)</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">CLOSING OF THE FILLING OPENING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">TIGHTENING OF THE PROSTHESIS BAG</div> <div style="border: 1px dashed black; padding: 2px; margin-bottom: 2px;">STITCHING ELEMENTS ON REAR BLOCK</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">CURING UNDER VACUUM</div> <div style="border: 1px solid black; padding: 2px;">CUTTING-OFF EXCESSIVE FOIL</div> </div>			

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A method of manufacturing a foil-wrapped breast prosthesis and a shaping tool for use in performing the method.

The invention relates to a method of manufacturing a foil-wrapped breast prosthesis with a filling consisting of a curable compound, preferably a silicone compound, by which at least two foil sheets of a formable plastic material are joined for producing a prosthesis bag, leaving at the joint a filling opening,

10 through which the bag is filled with a quantity of said compound and the filling opening is sealed after air bubbles have been expelled,

the filled prosthesis bag is placed in a mould having a first mould part with an open mould cavity corresponding to the desired shape of the front of the prosthesis, the bag being positioned with respect to the mould cavity and secured to the mould,

whereafter the filling is cured and the moulded prosthesis is removed from the mould.

20 The invention also relates to a shaping tool for use in performing the method.

From DE-C2-33 36 279 and US-B1-4.249.975 methods of manufacturing breast prostheses are known by which injection of the silicone compound used as filling is performed under pressure during the actual curing process, which is performed in a closed mould. In this connection, it is known from said DE publication to bring the walls of the prosthesis bag into contact with the walls of the mould cavity by applying vacuum before injecting the silicone compound.

To avoid the disadvantages by injecting the silicone compound under pressure during the actual curing process, a manufacturing method of the above mentioned kind is suggested in GB-A-2 257 387, by which the prosthesis bag is filled before being placed in the curing mould, which also in this case is closed, the actual mounting taking place under application of vacuum.

In a method of the above mentioned kind, the manufacturing can be performed in practice e.g. by welding together two sheets of polyurethane foil, which have been pre-shaped for forming the front and the rear side, respectively, of the prosthesis, into a prosthesis bag by means of a contour welding tool, thereby leaving a gate for use in filling the curable prosthesis mass, which usually consists of a vulcanizable silicone compound. By the filling, a predetermined volume of the filling compound is admitted to the prosthesis bag by means of conventional mixing and dosing equipment, whereafter the gate is sealed by high-frequency or hot welding, possibly after having expelled air bubbles.

However, for the method according to the above mentioned GB patent application, an over-charging of the prosthesis bag is required to obtain a fully moulded front with an intended anatomic shape with a nipple, which generally results in an unintentional thickening of the prosthesis edge, the prosthesis thus not fitting tightly to the body.

The purpose of the invention is to provide a method by which the above mentioned problem can be met, and a shaping tool which to a considerable extent eases the handling of a prosthesis bag by placing and fixing it in a mould or a curing shell.

In this respect, according to the invention a method of the above mentioned kind is characterized in that the curing is performed without closing the mould cavity and while maintaining vacuum therein, at least in the beginning of the curing.

As the front of the prosthesis bag is kept in close contact with the wall of the mould cavity until the filling, or at least the part of it which is close to the wall, has cured, a considerably improved certainty is obtained for a fully moulded front with the desired shape corresponding to the mould cavity in the generally replace-

able first mould part and with thin edge parts, making the prosthesis fit well to the body.

At the same time, greater freedom in the elaboration of the rear side of the prosthesis is obtained, as an expansion of the prosthesis mass, as a result of thermal expansion during the curing, can be routed to the areas of the rear side which are less important to the appearance and function of the prosthesis.

As such method according to the invention can be performed without using a rear block, although such a rear block is applied in most cases to obtain a desired shaping of parts of the rear side of the prosthesis. The shaping of the rear side can also be utilized for adjusting the flexibility and elasticity of the prosthesis and, in case of large prostheses, possibly for adjusting the weight of the prosthesis.

The maintaining of vacuum during the curing must be of such duration that at least the part of the filling which is close to the front wall of the prosthesis has cured sufficiently. The duration of this period will depend partly on the size of the prosthesis, partly on the curing temperature. For practical reasons, it will often be preferable to maintain vacuum during the whole curing process.

The application of vacuum, at least in the beginning of the curing process, makes it unnecessary to dose the bag accurately to obtain well-defined front and rear sides, as the front is retained while at the same time the critical parts of the rear side can be shaped as desired. Hereby i.a. a sub-filling of the bag, due to a too small dosing or unfavourable thermal/curing conditions, can be shifted to less critical areas of the rear side.

In this way, better control of the quality of the finished product is obtained.

In addition, the rear side of the prosthesis can be elaborated with thin edges for obtaining form-fit contact with the body.

As by the method according to the invention shaping is preferably performed of the foil wall intended to form the rear side of the prosthesis, by bringing a rear block into contact with the prosthesis bag placed in the mould cavity 5 without closing this, such rear block can, for manufacturing self-supported breast prostheses, be utilized with advantage for placing stitching elements, which are subsequently transferred to the prosthesis bag by welding during the curing.

10 The shaping tool according to the invention provided for use in performing the method is of the type which comprises a first mould part having an open mould cavity corresponding to the desired shape of the front of a breast prosthesis, means for providing vacuum in said mould 15 cavity, and means for tightening the parts of the joined foil sheets in a prosthesis bag which are placed outside the joint placed at the opening edge of the mould cavity.

For obtaining simple handling of a prosthesis bag in connection with mounting and fixing, the shaping tool is 20 characterized in that said tightening means comprise a tightening frame connected with the first mould part, which frame has a packing for abutment with the parts of the foil sheets which are situated outside the opening edge the first mould part at the placing of the prosthesis bag in 25 the first mould part. In a preferred embodiment, the packing is elaborated in such a way that, after closing the frame with respect to the first mould part, it permits tightening of said foil sheets by stretching in only one direction in the packing plane away from the mould cavity, 30 but prevents movement of the foil sheets in the opposite direction, whereby the joint is made to be flush with the opening edge of the mould cavity. Hereby the otherwise rather complicated tightening process is facilitated and accurate positioning of the prosthesis bag in the mould 35 cavity is secured.

In the following the invention will be described in detail with reference to the drawing, in which

Fig. 1 is a flow diagram illustrating the main steps in the manufacturing of breast prostheses by the method according to the invention,

Figs. 2-4 are perspective views of an embodiment of a shaping tool according to the invention in three different positions,

Fig. 5 is a sectional view of the shaping tool shown in Figs. 2-4, and

Fig. 6 is a rear view of the finished breast prosthesis.

The flow diagram in Fig. 1 is a schematic illustration of the manufacturing of a self-supported breast prosthesis, the rear side of which must be provided with stitching elements, e.g. velcro elements for adhesive attachment to the skin of the user, in order to secure the prosthesis to the body.

In the embodiment shown, the manufacturing can, in a manner known per se, start by placing such velcro elements on the one of the two foil sheets which is intended to form the rear side of the finished prosthesis.

~~In the cases where it is required by the shaping of the prosthesis, preforming by thermoforming can subsequently be performed on the rear foil, which, like the front foil, may typically be a polyurethane foil.~~

However, these two initial steps are not necessary, as in many cases preforming of the rear side can be omitted and the invention offers the possibility of using a rear block, which is used for shaping the rear side of the prosthesis during the curing, for placing the velcro elements, which are subsequently transferred to the prosthesis bag by welding during the curing, thereby saving one production step.

The two foil sheets are welded together, possibly after having performed the two above mentioned initial steps, into a prosthesis bag by means of a contour welding tool of a kind known per se, this welding leaving a filling opening for filling the prosthesis mass, which preferably

consists of a vulcanizable silicone compound with various additives, e.g. dye.

It is hereby noted that by the method according to the invention, no preforming of the front foil is performed.

5 When the prosthesis bag has been marked, e.g. with type identifying mark and number, the silicone compound is filled into the bag by means of standard mixing and dosing equipment. It is hereby noted that by the method according to the invention, the filled quantity of the compound is
10 less critical than with known manufacturing methods, as a result of the increased degree of freedom with respect to shaping the rear side of the prosthesis.

After some time, possible small air bubbles in the filled compound, which has a gel-like consistency, are
15 expelled through the filling opening, e.g. by massaging the bag or by means of vacuum, as it is known from the above mentioned GB patent application, and the filling opening is then sealed by high-frequency or hot welding.

For production reasons, it may be advantageous to
20 store the prosthesis bags thus filled and sealed, which can be done by cold storage, as it is also explained in the above mentioned GB-A-2 257 387.

Finishing of the breast prosthesis is then done by placing a filled and sealed bag, which can be elaborated
25 with or without a preformed rear side and with or without stitching elements in the form of velcro elements, in a shaping tool and fixing it therein, which shaping tool can be designed as explained in further detail in the following.

30 At the fixing, the contour weld of the bag is made to be flush with the opening edge of a mould cavity in a lower part of the shaping tool by tightening the foil sheets, which mould cavity corresponds to the desired shape of the breast prosthesis, and hereby the front foil of the bag can
35 be brought into close contact with the wall of the mould cavity by applying vacuum to the mould cavity.

As explained in the following, a shaping tool having an open cavity is used for the method according to the invention during the subsequent curing process, during which vacuum is applied or applied vacuum is maintained at least long enough to cure the part of the silicone compound in the bag which is the closest to the front wall of the bag.

The open mould cavity results in a considerable degree of freedom with respect to post-shaping of the rear wall of the prosthesis, which can be done by means of a rear block forming part of the shaping tool.

The curing process, by which the silicone compound is vulcanized, is performed in a manner known per se in a curing oven at a temperature and for a period of time which depend on the silicone compound applied.

After the curing, the prosthesis is removed from the shaping tool and the parts of the joined foil sheets situated outside the contour weld are cut off, after which the prosthesis can be finished by washing, sorting and packing.

In the embodiment shown in Figs. 2-5, the shaping tool comprises a base frame with upright side parts 1 and 2, which at the front and at the back are connected with cross parts 3 and 4.

The base frame 1-4 is designed for detachable mounting of a first mould part 5, in which a hollow 6 forms an upwards open mould cavity with a wall shape corresponding to the desired front shape of the present breast prosthesis.

As it will appear most clearly from Fig. 5, an air duct 7 having a valve 8 is connected at the bottom of the mould cavity 6, which air duct is to be used when applying vacuum to the mould cavity through a non-illustrated hose coupling.

With a view to accurate positioning in the base frame, the mould part 5 is provided with a number of positioning

holes 8 for arrangement on guide pins on the top side of the base frame.

The top side of the mould part 5 is formed by a downwards curved top plate 9 having a shape determined by the desired contour of the rear edge of the prosthesis, so that a good fitting to the body of the rear side of the prosthesis can be obtained.

In the embodiment shown, a tightening frame 10 is pivotally connected with the top edge of the rear part 4 of the base frame by means of hinges 11.

As it can be seen most clearly in Fig. 3, the tightening frame 10 is designed as a principally rectangular frame, to the underside of which is attached a packing 12 of an elastic, semirigid packing material, e.g. silicone. The packing 12 is attached to the tightening frame 10 in such a way that it curves outwards in the direction away from the frame by a curvature corresponding to the curved top plate of the mould part 5.

The illustrated design of the packing 12 and the hinge connection of the tightening frame 10 with the rear part 4 of the base frame implies that the packing 12, when closing the tightening frame 10 on a filled prosthesis bag placed in the mould cavity 6, will be brought into contact with the parts of the joined foil sheets shown at 13 in Fig. 4 which are placed immediately outside the contour weld, in such a way that tightening of the foil sheets can only be done by stretching the sheets in only one direction in the packing plane, i.e. perpendicular to the pivot axis which is determined by the hinges 11 and in the direction away from this axis, as shown by the arrow 14 in Fig. 4, while the packing prevents movement of the foil sheets in other directions. Hereby a very accurate and reproducible positioning of the prosthesis bag in the mould cavity 6 is obtained.

After closing the tightening frame 10, this is fixed at the front part 3 of the base frame by means of locking handles 5.

In addition, a principally rectangular top frame 16 is pivotally connected with the tightening frame 10, on the underside of which top frame a rear block 17 can be detachably mounted, by which the rear wall of the prosthesis 20 can be given a desired shape during the curing, e.g. with the object of obtaining thin edge zones 21 within the contour weld of the prosthesis for providing optimum body fitting of a self-supported prosthesis.

As it will appear from Figs. 4 and 5, closing of the top frame 16, whether or not this is provided with a rear block, will not cause any closing of the mould cavity 6, but this is kept upwards open during the whole shaping process including the curing. At the closing, the top frame 16 is clamped to the front part 1 of the base frame by means of a spring-loaded latch 19.

As explained in the above and illustrated in Fig. 5, the rear block 17 may be provided with recesses 22 or the like for receiving velcro pieces in connection with production of self-supported prostheses, such velcro parts thus being transferred to the rear side of the prosthesis by welding during the curing.

Fig. 6 shows is a typical example of the design of the rear side of a breast prosthesis 20 manufactured by means of the method and the shaping tool according to the invention and with velcro parts 22 attached for providing safe attachment to the skin.

PATENT CLAIMS

1. A method of manufacturing a foil-wrapped breast prosthesis with a filling consisting of a curable compound, preferably a silicone compound, by which

at least two foil sheets of a formable plastic material are joined for providing a prosthesis bag, leaving at the joint a filling opening

through which the bag is filled with a quantity of said compound and the filling opening is sealed after air bubbles have been expelled,

the filled prosthesis bag is placed in a mould having a first mould part with an open mould cavity corresponding to the desired shape of the front of the prosthesis, the bag being positioned with respect to the mould cavity and secured to the mould,

whereafter the filling is cured and the moulded prosthesis is removed from the mould, characterized in that

the curing is performed without closing the mould cavity and while maintaining vacuum therein, at least in the beginning of the curing.

2. A method according to claim 1, characterized in that a shaping is performed of the foil wall of the prosthesis bag intended for forming the rear side of the prosthesis, by bringing a rear block into contact with the prosthesis bag placed in the mould cavity without closing this.

3. A method according to claim 2, characterized in that said vacuum is applied in connection with bringing the rear block into said contact.

4. A method according to claims 2 or 3 for manufacturing a self-supported breast prosthesis, characterized in that stitching elements are placed on said rear block and transferred to the prosthesis bag by welding during the curing.

5. A method according to any one of the preceding claims, characterized in that prior to the joining, a pre-shaping,

by thermoforming, is performed of the foil sheet intended to form the rear side of the prosthesis.

6. A method according to claim 5 for manufacturing a self-supported breast prosthesis, characterized in that stitching elements are placed on said foil sheet and sealed thereto during the pre-shaping, preferably by welding.

7. A method according to any one of the above claims, characterized in that during the shaping and the curing a nipple is elaborated in the front wall of the prosthesis bag by means of a hollow corresponding to this in said mould cavity in the first mould part.

8. A method according to any one of the above claims, characterized in that the joint is provided by contour welding.

9. A shaping tool for use in performing the method according to any one of the preceding claims, comprising a first mould part (5) having an open mould cavity (6) corresponding to the desired shape of the front of a breast prosthesis, means (7, 8) for providing vacuum in said mould cavity, and means for tightening the parts of the joined foil sheets in a prosthesis bag which are situated outside the joint placed at the opening edge of the mould cavity, characterized in that said tightening means comprise a tightening frame (10) connected with the first mould part, which frame has a packing (12) for abutment with the parts of the foil sheets which are situated outside the opening edge of the first mould part at the placing of the prosthesis bag in the first mould part.

10. A shaping tool according to claim 9, characterized in that said packing (12) is designed in such a way that, after closing of the frame (10) with respect to the first mould part (5), it permits tightening of said foil sheets by stretching in only one direction in the packing plane away from the mould cavity (6), but prevents movement of the foil sheets in the opposite direction, whereby the joint is made to be flush with the opening edge of the mould cavity.

11. A shaping tool according to claim 9 for use in performing the method according to claim 2, characterized in that at least one rear block (17) is connected with the tightening frame (10) for use in performing said shaping of the rear wall of a prosthesis bag placed in the first mould part.

12. A shaping tool according to claim 11, characterized in that said rear block is connected with the tightening frame (10) in such a way that said shaping can be performed in continuation of said tightening.

13. A shaping tool according to claims 11 or 12, characterized in that the first mould part (5), the tightening frame (10), and said rear block (17) are hinged to each other by a substantially congruent hinge axis.

14. A shaping tool according to any one of the claims 9-13, characterized in that the parts of the first mould part (5) and of the tightening frame (10) intended for abutment with a prosthesis bag are black-oxidized or -anodized metal parts.

15. A shaping tool according to claims 11, 12, or 13, characterized in that said rear block (17) is elaborated for receiving stitching elements (22) with a view to positioning these against the rear wall of a prosthesis bag and subsequently welding them thereto during the curing.

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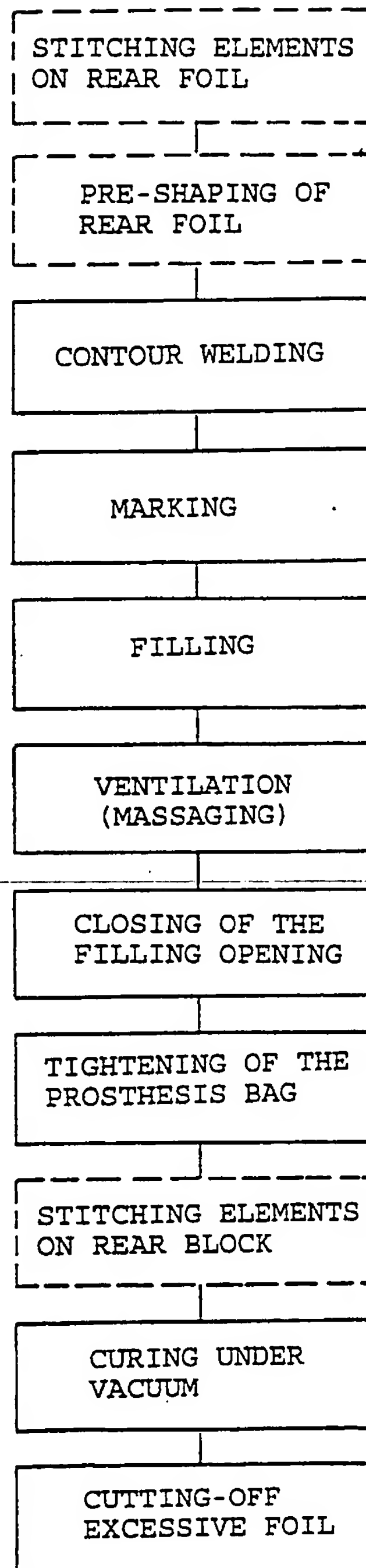


FIG. 1

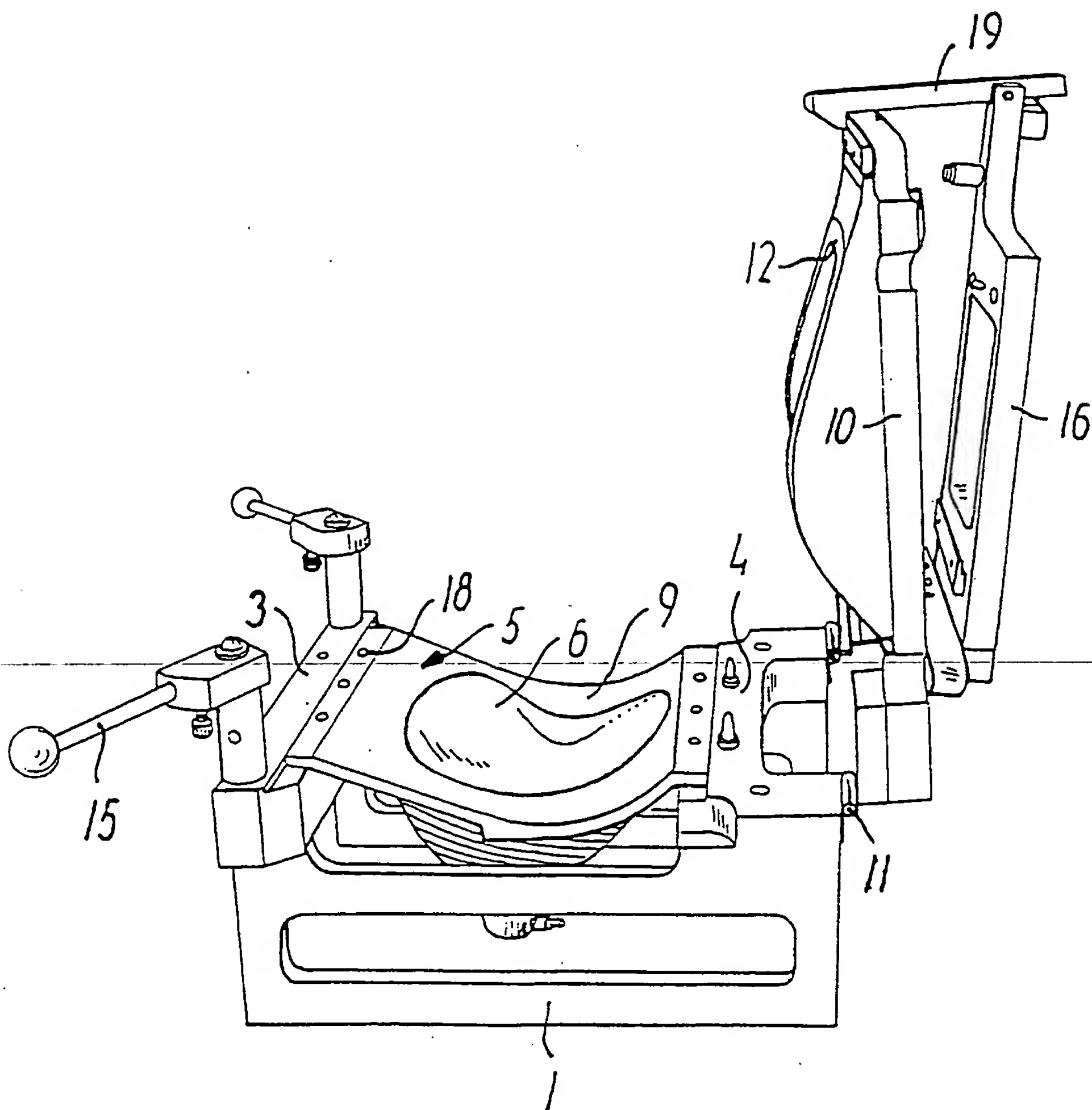


FIG. 2

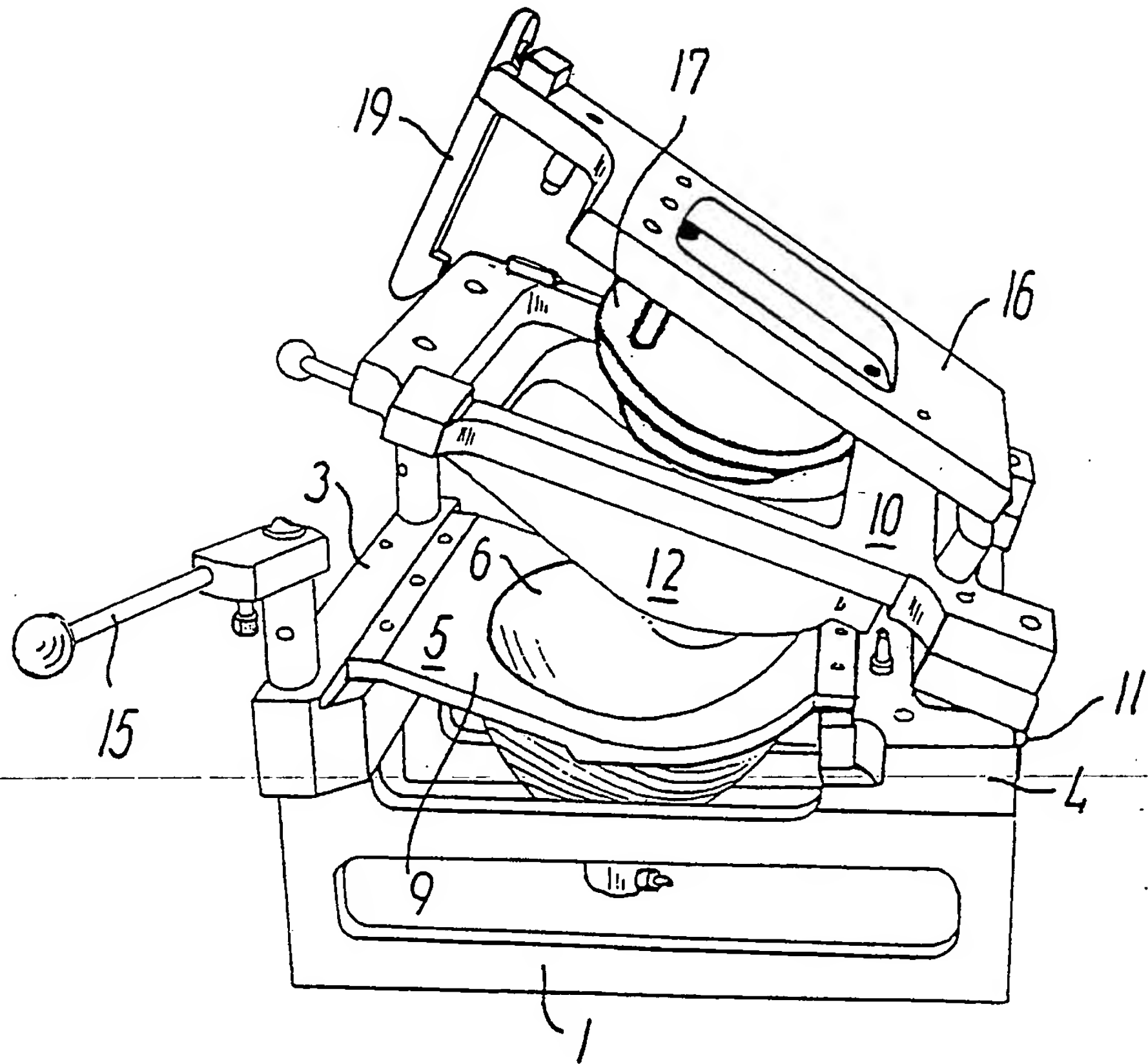


FIG.3

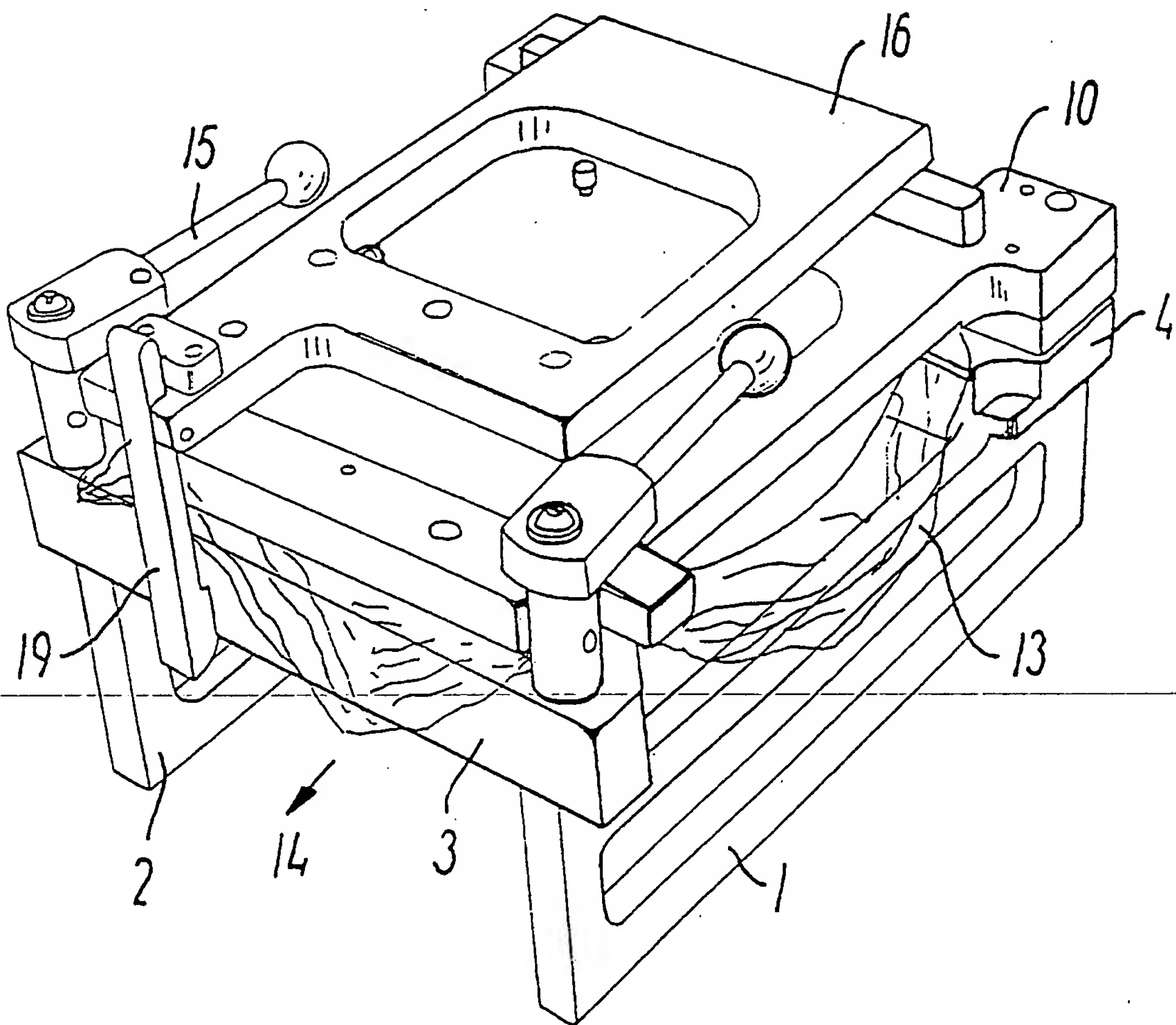


FIG. 4

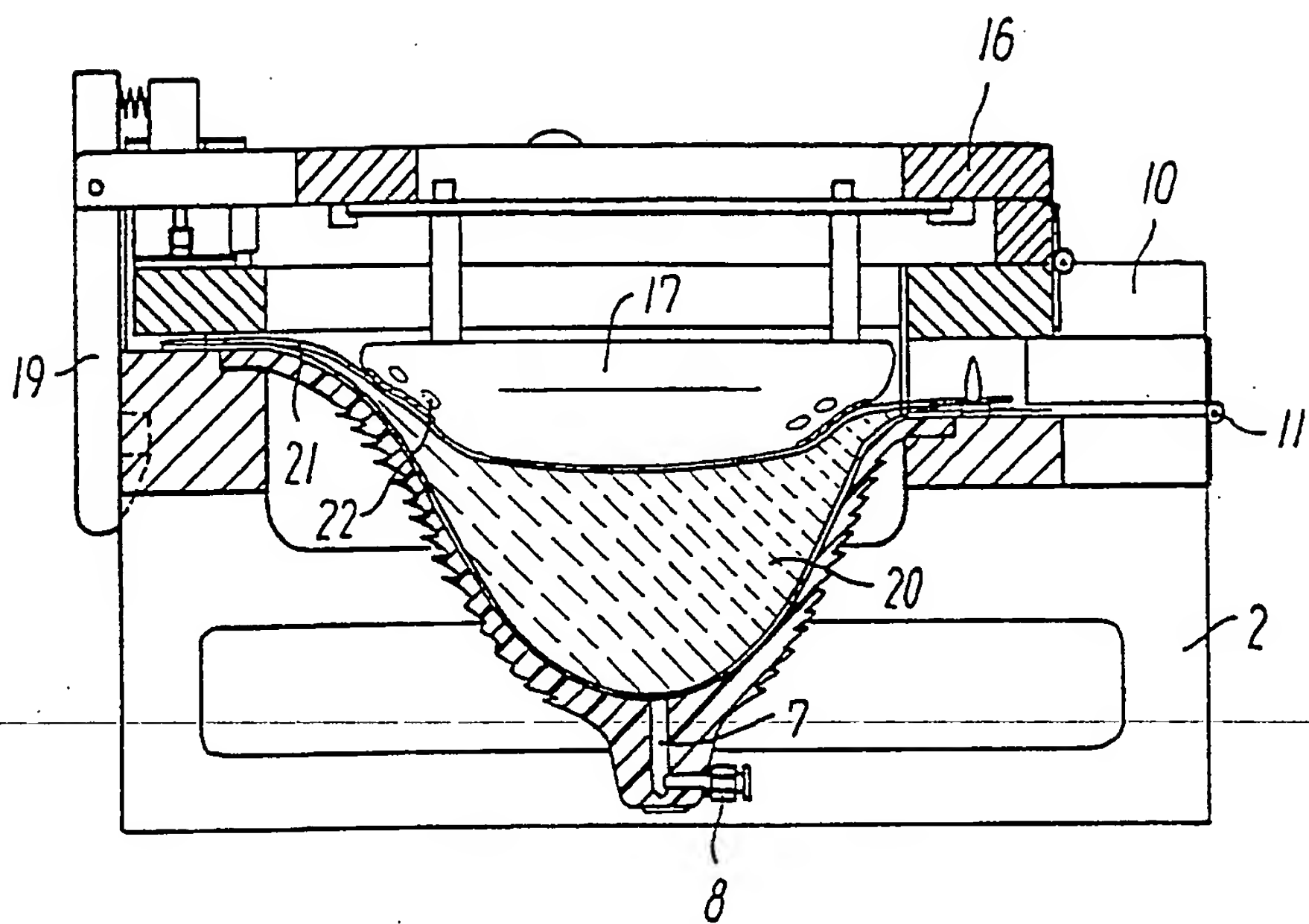


FIG. 5

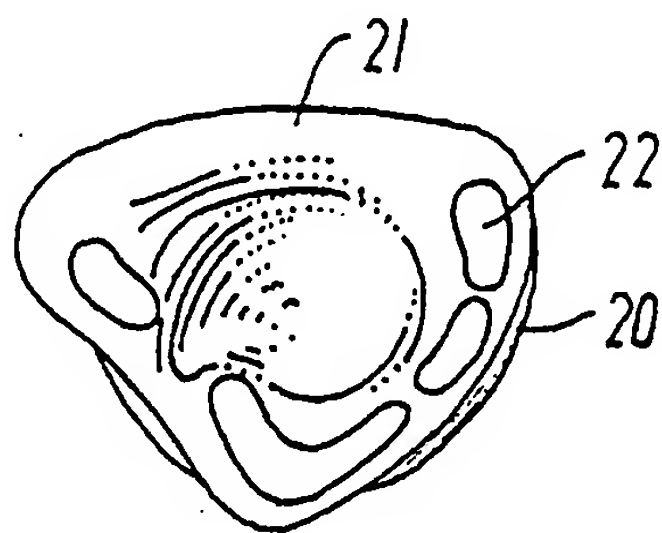


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 94/00479

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/52, B29C 51/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F, B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP, A2, 0429029 (FIRMA KUNSTSTOFFTECHNIK DEGLER GMBH), 29 May 1991 (29.05.91), column 8, line 10 - column 9, line 28, figures 1-3	9-13
A	--	1-3,7-8
X	DE, C2, 3336279 (KUNSTSTOFFTECHNIK DEGLER GMBH), 9 January 1986 (09.01.86), column 6, line 25 - column 7, line 56, figures 1-2	9-13
A	--	1-8
X	US, A, 4247351 (CORNELIUS RECHENBERG), 27 January 1981 (27.01.81), column 3, line 1 - line 45, figure 1	9-13
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Further documents are listed in the continuation of Box C.



See patent family annex.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4249975	10/02/81	AU-A- 4380272	03/01/74
		CA-A- 1021997	06/12/77
		CA-A- 1033615	27/06/78
		CA-A- 1058960	24/07/79
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		CA-A- 1071468	12/02/80
		CA-A- 1086561	30/09/80
		CA-A- 1096237	24/02/81
		DE-A,C- 2230876	11/01/73
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		GB-A- 1402722	13/08/75
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		GB-A- 1402724	13/08/75
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